

**Nisqually Indian Tribe**

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

April 21, 1999

To whom it may concern,

This letter is in response to Docket No. 98P-054, initiated by the Center for Science in the Public Interest (CSPI), dated June 29, 1998. The petition is a formal request that the Food and Drug Administration (FDA) adopt regulations to ensure levels of the bacteria *Vibrio vulnificus* are non-detectable in raw molluscan shellfish intended for sale.

We at the Nisqually Tribe share a concern for the illnesses and deaths caused by this bacteria, but feel this petition penalizes the entire country, when clearly, the illnesses and deaths caused by *V. vulnificus* have ONLY been positively linked to oysters coming from Gulf states. *Vibrio vulnificus* is a cosmopolitan bacterium, found throughout the east and west coasts of the United States in marine environments. As this is a "normal" part of many marine ecosystems in the country, assigning a raw shellfish level of "non-detectable" is unrealistic. Although *V. vulnificus* is indeed found in Washington waters, it is extremely unlikely to encounter bacterial concentrations which pose a threat to humans who consume infected raw shellfish. There are NO documented cases identifying Washington state as a positive supplier of raw shellfish that was associated with a *V. vulnificus* illness or death. This fact begs the question of why should the entire U.S. be penalized for illnesses and deaths that occur in a specific part of the country??? The logic being asserted by the CSPI, we feel, is extremely flawed and not representative of west coast shellfish growing operations.

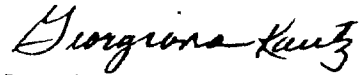
The Nisqually Tribe feels there should be more background investigation on confirming the sources of *V. vulnificus* infected shellfish, before a widespread regulation is enacted. Better yet, we feel this problem should be micro-managed, state by state, instead of bluntly and non-intensively addressing the problem. Currently, the Interstate Shellfish Sanitation Conference (ISSC) which is Washington State's forum for these issues, is considering new restrictions concerning *V. vulnificus*. The Gulf states, which have repeatedly been confirmed to be associated with *V. vulnificus* outbreaks, illnesses, and deaths, should be held responsible to develop practices which eliminate or severely decrease these instances. Washington state should not be held hostage because Gulf coast states cannot effectively implement public safety measures concerning raw shellfish consumption.

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We appreciate the opportunity to comment on this matter, as it would greatly impact our individual Tribal members, commercial fishermen, shellfish programs.

Sincerely,

A handwritten signature in cursive script that reads "Georgiana Kautz".

Georgiana Kautz
Nisqually Indian Tribe
Fisheries Manager